ABSTRACT

Development and Validation of HPLC-ELSD Method for Determination and Stability Indicating Method of Sucralfate

Sucralfate or aluminum sucrose octasulfate commonly used as a cytoprotective agent for peptic ulcer. To ensure quality, efficacy and safety of sucralfate for treatment, it is necessary to develop and validate method for the analysis of sucralfate. The objective of this study was to develop and validate a HPLC-ELSD method for analysis of sucralfate in raw material and suspension dosage form. The chromatographic condition was achieved using Phenomenex Luna ODS3 column (250 x 4.6 mm i.d.) with 5µm particle size, mobile phase was prepared by mixing acetonitrile : TFA 0.1 % (50:50) in isocratic elution at the flow rate of 0.8 ml/min. The column temperature was 25^{o}C and the injection volume was 10 µl. The temperature of nebulization and evaporation of the ELSD was set at 70^{o}C and 30^{o}C, respectively and gas flow rate at 1.8 SLM. This method was found to be selective and accurate with % recovery between 92% and 102 %. The precision was expressed as % RSD and the result was ≤ 2 %. The retention time of sucralfate is 2.29 min with a run time of 4 min. The linearity of the proposed method was investigated in the range of 300 – 800 µg/ml with coefficient correlation (r) and Vxo was 0.999 and 0.765, respectively. All the validation parameters like selectivity, linearity, range, accuracy and precision met the acceptance criteria according to ICH guidelines. Overall, the proposed method is rapid, simple and selective for detection and determination of sucralfate.

Keywords : Development method, validation method, sucralfate analysis, HPLC-ELSD, sucralfate suspension